



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION  
OFFICE OF PESTICIDE PROGRAMS REGISTRATION DIVISION (7505P)

~~DOCUMENT CONTAINS CONFIDENTIAL BUSINESS INFORMATION~~

**DP BARCODE No.:** D446467; **FILE SYMBOL No.:** 62719-TGN; **PRODUCT NAME:** NativeKlean; **DECISION No.:** 538667; **PC Code(s):** 005209, 030019; **ACTION CODE:** R300; **FOOD Use:** Yes; **COMPANY:** Dow Agrosiences LLC Corporation

**DATE OUT:** April 19, 2018

**SUBJECT:** End Use Product Chemistry Review  
Product Name: NativeKlean

**FROM:** Shyam Mathur, Ph. D  
Team Leader  
Chemistry, Inerts & Toxicology Assessment Branch (CITAB) /RD (7505P)

**TO:** Sarah Meadows / Kathryn Montague, RM 23, Herbicide Branch / RD (7505P)

**INTRODUCTION:**

The registrant has submitted an application for the registration of the new end use product "Native Klean". The registrant has submitted a CSF for basic formulation & two alternate formulations #1 & #2 (all dated January 23, 2018). The registrant has claimed that the proposed product is substantially similar / identical to the registered product with Reg. No. 62719-630 and has, therefore, cited the supporting group A & group B product chemistry data with MRID No(s) 48173001 & 48173002. The cited PC data were reviewed previously by the Agency (see PCR dated 02-11-2011; DP382305) and were found to be acceptable. CITAB has been asked to determine the acceptability of the proposed basic & alternate CSF's, and the supporting cited product chemistry data and also determine similarity to the registered product.

**SUMMARY OF FINDINGS:**

1. Name of Active Ingredient(s): Triisopropylamine salt of Aminopyralid [ 2-pyridine carboxylic acid, 4-amino-3,6-dichloro (8.24%)] and DMA salt of 2, 4-Dichlorophenoxy acetic acid (41.26%)
2. Has the registrant claimed substantial similarity to a registered product?  
  
[X] Yes; [ ] No; [ ] NA; if yes give the registration number of the cited product.  
  
EPA Reg. No: 62719-630
3. All of the source materials of the active ingredient are derived from registered sources- [X] Yes [ ] No
4. All inert ingredients have been screened by CITAB (Inert group) and found to be approved for the proposed labeled uses.

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5. Confidential Statement of Formula(s):

☒ Basic - Dated: 01-23-2018; Re-submitted - Dated:

☒ Alternate CSF's #1 & #2 – Both Dated: 01-23-2018; Re-submitted alt CSF – Dated:

Alternate CSF(s) complies with 40CFR§152.43: ☒ Yes; ☐ No; ☐ NA

6. Product label

- a. Ingredient statement: Nominal concentration of AI listed on CSF(s) concurs with product label (PR Notice 91-2).

☒ Yes; ☐ No; if not, explain below:

Is the sub statement in compliance with PR Notice 97-6 (inert ingredient vs other ingredients)

☒ Yes; ☐ No; if not, explain below:

Metallic equivalent: ☐ Yes ☒ NA

Soluble arsenic: ☐ Yes ☒ NA

Isomeric ratios: ☐ Yes ☒ NA

Acid Equivalent: ☒ Yes ☐ NA:

Aminopyralid (2-pyridine carboxylic acid, 4-amino-3,6-dichloro-) acid equivalent = 4.28% (0.41 lbs/gal)

2, 4-D acid = 34.25% (3.33 lbs/gal)

- b. Health related sub statements: Product contains?

Petroleum distillate at > 10%: ☐ Yes ☒ No ☐ NA

Methanol at > 4%: ☐ Yes ☒ No ☐ NA

Sodium nitrate/Sodium nitrite ☐ Yes ☒ No ☐ NA

- c. Physical chemical hazard statement: Product label requires a statement per 40 CFR §156.78 for: flammability, explosive potential or electric insulator breakdown?

☐ Yes; ☒ No

Is the sub statement in compliance with PR Notice 98-6 (Total Release Fogger)?

☐ Yes; ☐ No; ☒ NA; if not, explain below

- d. Label requires an additional Storage and Disposal statement:

☐ Yes; ☒ No; if yes explain below:

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7. Group **A**: Product Chemistry Data cited from Reg. No. 62719-630

CITAB's determination of the acceptability for the proposed product is listed in the tables below.

Guideline No.	Study Title		Data cited		CITAB's Assessment of Data	MRID Nos. Cited
			Yes	No		
830.1550	Product Identity & Composition		cited		A	48173001
830.1600	Description of materials used to produce the product		cited		A	48173001
830.1650	Description of formulation process		cited		A	48173001
830.1670	Discussion on the formation of impurities		cited		A	48173001
830.1700	Preliminary analysis				NA	
830.1750	Certified limits (158.350)	cited	X		A	Basic CSF dated 01-23-2018 Non-standard certified limits have been proposed for few inert ingredients with justifications (in alt CSF)
		Proposed Limits	X		A	
		Justification for wider limits				
830.1750			X		A	
830.1800	Enforcement analytical method		Cited		A	48173001 HPLC-UV (230 nm) External standard calibration. Method validation provided.

A = Acceptance, N = Not Acceptable, G = Data Gap, W = Waiver Request, I = In Progress, NA = Not Applicable; U = Upgradeable.

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8. Group **B**: Product chemistry data cited from Reg. No. 62719-630

Guideline No.	Study Title	Value or Qualitative Description	CITAB's Assessment of Data	MRID Nos. cited
830.6303	Physical State	Liquid at 22°C	A	48173002
830.6315	Flammability	>100°C	A	48173002
830.6316	Explodability	Impact explodability: Not impact sensitive. (ASTM D2540-70) Thermal explodability: An onset of an incomplete exothermic event was observed at 256 °C. (ASTM E537-86)	A	48173002
830.7000	pH	6.69 @ 23°C (1% w/w dilution)	A	48173002
830.7300	Density (units)	1.173 g/cc (9.78 lbs/gal) at 20°C	A	48173002
830.7100	Viscosity	Newtonian: 26.55 mPa·s at 19.8 °C 10.16 mPa·s at 40.0 °C	A	48173002
830.6317	Storage stability	No data submitted	G	48173002
830.6320	Corrosion characteristics	No data submitted	G	48173002
830.6314	Oxidation/reduction	No temperature change >5°C was observed	A	48173001

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**CONCLUSIONS:**

CITAB has reviewed the product chemistry data submitted for the end-use product and has concluded that:

**A. Substantial similarity to the cited product (Reg. No. 62719-630) from Product chemistry view point**

- ☐ Similar
- ☐ Not similar, give reasons:
- ☒ Identical
- ☐ Not identical
- ☐ Not Applicable

**B. Confidential Statement of formula**

- 1. Basic CSF (dated: 01-23-2018)
  - ☒ Acceptable
  - ☐ Not Acceptable:
  - ☐ Not Applicable
- 2. Alternate CSF #1 & #2 (both dated:01-23-2018)
  - ☒ Acceptable
  - ☐ Not Acceptable:
  - ☐ Not Applicable

**C. Group A Product Chemistry Data**

- ☒ Acceptable
- ☐ Acceptable with the exception of the guideline:
- ☐ Not acceptable
- ☐ Not required
- ☒ Data cited

**D. Group B Product chemistry data**

- ☐ Acceptable
- ☐ Not acceptable
- ☒ Acceptable with the exception of the guidelines 830.6317 (ss) & 830.6310 (cc). The registrant is recommended to generate one-year study at RT in commercial container or has option to generate accelerated studies (2 weeks at 54°C) stored in commercial containers. The results of the studies must be submitted to the Agency for evaluation.
- ☐ Not required
- ☒ Data cited
- ☐ Waiver requests: Acceptable ☐; Not Acceptable ☐; Not Applicable ☒

**E. Product Label/Draft Label: Recommendations – Yes ☐; No ☒**

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